

**REMARKS**

The Official Action of March 17, 2004, made final, has been carefully studied. The claims in the application remain as claims 1, 2 and 4-17, and it is proposed above that these claims be amended. Applicants continue to maintain that their claims define novel and unobvious subject matter warranting their allowance. Accordingly, applicants respectfully request favorable reconsideration, entry of the amendments presented above, and allowance.

Applicants also **request withdrawal of the finality of the last Office Action.** The PTO agrees (bottom paragraph on page 2 of the final Action) that the previous Office Action was erroneous in its reliance on JP '824 instead of JP '122. Accordingly, because the previous rejection was erroneous, the new rejection was not required because of any amendments presented by applicants, per MPEP 706.07(a). Under these conditions, the present Office Action should not be "final". **Applicants request that such finality be withdrawn as being premature, per MPEP 706.07(c).**

In the amendments presented above, the quantity of titanium oxide is proposed to be included, such amount being 0.1 - 1.5% by weight based on the total amount of capsule

shell components, support being found at page 16, lines 13-17 of the specification. In addition, it is proposed above to include the amount of yellow and/or red iron oxide, such being 0.01-1.0% by weight, support being found in the specification at page 7, lines 14-16. Additionally, it is proposed above to recite the amount of caramel, support being found for 0.05-1.5% by weight at page 7, last line to page 8, line 5. In addition, it is proposed to specify the thickness of the capsule shell, same being 200  $\mu\text{m}$  - 600  $\mu\text{m}$ , support being found at page 9, lines 20-25 of applicants' specification.

Claims 1, 4-6 and 10-16 have been rejected as obvious under §103 from JP '532 (Teijin) in view of Hegasy, JP '122 (Ogawa) and JP '641 (Toyo). This rejection is respectfully traversed.

Applicants first describe and discuss each of these citations individually, and then their proposed combination.

(i) Re: JP 3264532 (Teijin)

The rejection states that JP '532 teaches soft capsules containing an active vitamin D. However, despite having precisely reviewed the entire document, applicants cannot find that JP '532 contains any teaching about which material could be used for the capsule shells or how the capsule shells could be prepared. Furthermore, JP '532

neither describes nor suggests any method for producing soft capsules, or even any references relating to such methods. Therefore, it cannot be correctly said at all that such a document teaches soft capsules containing an active vitamin D.

(ii) Re: USP 4693892 (Hegasy)

As is apparent from the claims and the entire description of Hegasy, this document discloses that soft capsules containing  $\beta$ -carotene and iron oxide, optionally containing titanium dioxide, have an outstanding light protection effect. In other words, "an outstanding light protection effect" indicated in Hegasy resulted from the presence together of  $\beta$ -carotene and iron oxide, optionally with titanium dioxide; Hegasy neither discloses nor suggests whether or not a similar effect is obtainable when  $\beta$ -carotene, the essential feature of Hegasy, is deleted, and the person of ordinary skill in the art would likely conclude that no "outstanding light protection effect" would be obtained without  $\beta$ -carotene being present.. Furthermore, Hegasy does not specifically disclose what the "outstanding protection effect" is which results from the combination of  $\beta$ -carotene and iron oxide, optionally with titanium dioxide, which means that it is doubtful whether such an "effect" is at a practically recognizable level or not.

(iii) Re: JP 4046122 (Ogawa JP '122)

JP '122 relates to "hard capsules" and does not describe "soft capsules" at all; this is confirmed by reviewing the full English translation of the specification of JP 4'122. The definition of "hard capsules" and "soft capsules" are given in pages 536-537 of the 4<sup>th</sup> edition of European Pharmacopoeia, copy attached, indicating that soft capsules are of a different formulation from that of hard capsules.

(iv) Re: JP '641 (Toyo)

Toyo JP '641 only discloses, as previously pointed out, that caramel together with an amino acid can be used to provide a light-shielding gelatin capsule. Again, there is nothing in Toyo JP '641 which would have led the person of ordinary skill in the art to combine caramel with anything other than an amino acid, let alone with titanium oxide.

(v) Re: The Proposed Combination

It should be clearly evident from what is pointed out above and clearly taught by each of the citations, that even if the proposed combination were obvious, it would not reach applicants' claims. More particularly, the three subsidiary references simply do not make up for all of the deficiencies of Teijin JP '532 pointed out above. As the

proposed combination would not reach the claimed subject matter even if the combination were obvious, it clearly follows that what is recited in applicants' claims is not made obvious by the proposed combination.

Moreover, because of the various differences among the citations as pointed out above, wherein different combinations are taught to provide particular results, but not applicants' combination, and wherein not all the citations even relate to soft capsules, applicants continue to maintain that the combinations would not have been obvious, and certainly would not have been obvious in such a way as to lead the person of ordinary skill in the art to the claimed subject matter.

(vi) Re: The Present Invention

The present invention is the first to have achieved soft capsule formulations of active vitamin D<sub>3</sub> with excellent **stability to light and heat, as well as good discrimination,** which can be prepared by a process well-suited to practical production. Only the claimed specific combination (not those of the prior art) can accomplish such advantages of the soft capsule formulation of the present invention. The excellent discrimination of the soft capsules of the present invention

is apparent from the results described in Examples of applicants' specification.

On the other hand, none of the citations disclose or suggest soft capsules containing active vitamin D or the effects (i.e. the excellent stability to light and heat, and good discrimination) provided by the combination of the components recited in the amended claims (i.e. the combination of titanium oxide and one or more of yellow iron oxide, red iron oxide and caramel).

Even if the components of the capsule shells of the present invention could be inferred from the disclosure of the citations, the newly added specific features (i.e. the amount of each component and the thickness of the capsule shells), which contribute to the above-described effects, are neither disclosed nor suggested in the citations. Therefore, the soft capsule formulations of the present invention, which exhibit excellent practical effects, are unobvious from the disclosure of the citations.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 2-7 and 17 have been rejected as obvious under §103 over Teijin JP '532 in view of Parke Davis JP '242,

Hegasy and Toyo JP '641. This rejection is respectfully traversed.

Teijin JP '532, Hegasy and Toyo JP '641 have all been discussed above as well as previously. Parke Davis JP '242 has been discussed previously, and applicants' previous comments on these references individually and collectively are respectfully repeated by reference.

For the same reasons as pointed out above, the proposed combination, even if it were obvious (contrary to applicants' position) would not reach the claimed subject matter. In addition, the citations are sufficiently individually diverse from one another that the only suggestion for their combination comes from applicants' own disclosure, which disclosure of applicants was not available to the person of ordinary skill in the art at the time the present invention was made. Because soft capsules and hard capsules are fundamentally different, the person of ordinary skill in the art would not abstract something from one for incorporation into the other.

In addition, because one combination of two ingredients produces a particular effect, the knowledge of that effect does not make it obvious to take only one of those components and add it to something else and expect the same (or similar) results. The prior art simply provides no

reasonable expectation of applicants' results, let alone the improvements achieved by the present invention as pointed out above and in applicants' specification.

Applicants respectfully request withdrawal of the rejection.

Claims 1, 4-6, 10-15 and 17 have been rejected as obvious under §103 from Teijin JP '532 in view of Ogawa JP '122, Toyo JP '641 and Hegasy. This rejection is respectfully traversed.

Again, the references have been discussed individually and collectively, and again their combination (even if obvious) would not reach the claimed subject matter; in particular, the subsidiary references do not make up for all the deficiencies of Teijin JP '532 as pointed out above.

In addition, for reasons similar to those pointed out above, the proposed combination would not have been obvious to the person of ordinary skill in the art at the time the present invention was made, because it is only applicants' specification (not available to the person of ordinary skill in the art at the time the present invention was made) which suggests taking one element of two-element combinations and recombining them as claimed. The prior art provides no reasonable expectation that applicants' combination would even



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begin to work, let alone provide the improved results which have been demonstrated in applicants' specification.

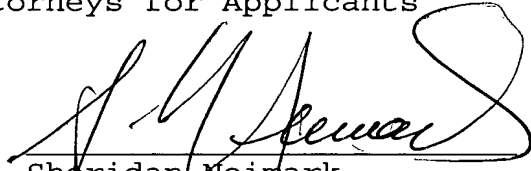
The rejection should be withdrawn. Such is respectfully requested.

Favorable reconsideration, entry of the present amendment and allowance are earnestly solicited.

Respectfully submitted,

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